

REMARKS

Status of the Claims

Claims 113 through 148 are pending. Claims 115-118 and 126-146 were previously withdrawn. With the entry of this response, claim 113 is amended, claim 114 is cancelled and claims 147 and 148 are new.

Support for Claim Amendments

Claim 113 is amended to clarify that the fractional adhesion layer covers only a fraction of the total area of a surface barrier layer, where the fraction is less than 1. Applicants submit that this is a clarification, not a change in claim scope. Fractional and fraction would be meaningless in the claim if they were permitted to encompass 3/3 or 4/4. In other words, the fractional adhesion layer cannot cover 100% or more of the area of a barrier layer. Support for this amendment may be found in Figures. 2A-2C, showing adhesion layers **4** in contact with a barrier layer **2**, such that the entire barrier layer is not covered. Mathematically, therefore, the fraction of the total area of a side of the barrier layer must inherently be less than 1. Support may also be found in p. 12, lines 4-10 of the application (para. [0062] of the published application), which states that the patterns of the adhesion layer may be discontinuous (to minimize the amount of adhesive used), which , mathematically, requires that the fraction of the total area of a side of a barrier covered by the adhesion layer must inherently be less than one .

New claims 147 and 148 are directed to a patch in accordance with claim 113, wherein the fractional adhesion layer is a discontinuous pattern and, more particularly, the pattern comprises unconnected dots or lines. Support for these claims may be found in Fig. 2C and in p. 12. lines 6-8 of the application.

Objection of Claim 114

Claim 114 has been objected to as being in improper dependent form for failing to further limit the subject matter of claim 113 from which it depends. The cancellation of claim 114 obviates this objection.

Rejections Under 35 U.S.C. § 112, para. 2 – Indefiniteness

Claim 113 has been rejected under 35 U.S.C. § 112 as being indefinite for failing to point out and distinctly claim the “metes and bounds” of “an adhesion area that is a fraction of the total area of a side of the barrier layer.” As amended, claim 113 clarifies that the fraction of the total area covered by the adhesion layer is less than 1. This establishes an upper boundary for the area covered by the fractional adhesion layer, which must be less than -and cannot be equal to- the total area of the barrier layer. Furthermore, the claim also defines a lower limit because it requires a fractional adhesion layer, which must cover at least some portion of the barrier layer. Therefore, as amended, claim 113 has both upper and lower limits.

In light of the amendment to claim 113 and the arguments above, Applicants respectfully submit that claim 113 is definite and clear. Withdrawal of the indefiniteness rejection is requested.

Rejections Under 35 U.S.C. § 102 – Anticipation

To anticipate a claim under 35 U.S.C. § 102, a prior art reference must teach every element of that claim. MPEP § 2131. None of the references cited by the Examiner meet this requirement.

Rejections Based on 2002/0160035 (*035)

Claims 113, 119 and 122 have been rejected under 35 U.S.C. § 102(a)/(e) as being anticipated by U.S. patent publication 2002/0160035 (*035) to Fotinos. However, the cited prior art does not meet all the claim limitations.

The Examiner submits that Fig. 1 of the ‘035 publication shows an adhesive layer that covers only a fraction of a barrier layer, thereby reading on the “fractional adhesion layer” limitation of claim 113. Claim 113, however, makes clear that the fraction of the barrier layer covered by the adhesive layer must be less than 1. In other words, the fractional adhesion layer of amended claim 113 cannot cover the entire barrier layer. Fig. 1 of the ‘035 publication, on the other hand, shows an adhesive layer 2 that covers the

entire total area of the boundary layer 4. ‘035 publication, paras. [0041] and [0045]. The adhesive layer of the figure clearly extends to the limits of the boundary area.

Moreover, Fig. 1 of the ‘035 patent does not teach a barrier layer with a first side attached to an active layer and an opposite side attached to a separate fractional adhesion layer. Rather, the active layer 3 in Fig. 1 is separated from the barrier layer 4 by the upper adhesion layer 2. ‘035 patent, p. 3, para. [0041]. The ‘035 patent as a whole does not disclose a barrier layer in simultaneous contact with separate fractional adhesion and active layers on opposite sides of the barrier layer, and therefore, does not disclose the same elements in the same arrangement as the instant claims.

Because, as demonstrated above, the ‘035 publication does not disclose or suggest every limitation and the arrangement of the instant claims, independent claim 113 and claims 119 and 122, which depend from claim 113, are patentably distinguishable and allowable over the ‘035 publication.

Rejections Based on US 4,874,129

Claims 113, 119 and 122 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. patent 4,874,129 (‘129) to DiSapio et al. However, the cited prior art does not meet all the claim limitations.

The Examiner asserts that Fig. 6 of the ‘129 patent shows an adhesive layer that covers only a portion of a barrier layer, thereby meeting the “fractional adhesion layer” limitation of the instant claims. Claim 113, however, includes a limitation that the fraction of the barrier layer covered by the adhesive layer must be less than 1. In other words, the fractional adhesion layer of amended claim 113 cannot cover the entire barrier layer. Fig. 6 of the ‘129 publication, on the other hand, shows an adhesive layer 60D that covers the entire total area of a side of a rate controlling membrane 60E and, presumably, a release liner 60C. ‘129 publication, col. 16, lines 6-10. Even assuming for the sake of argument that the 60E and 60C layers in Fig. 6 of the ‘129 patent are equivalent to the barrier layer of the present invention, the adhesive layer of the figure clearly extends to the limits of a side of both 60E and 60C. Therefore, Fig. 6 of the ‘129 patent does not teach a fractional adhesion area that is a fraction of the total area of a side of a barrier layer, where the fraction is less than the entire barrier layer.

In addition, Fig. 6 does not disclose a barrier layer with a side attached to an active layer. The barrier layer of the instant claims cannot be penetrated by volatile compounds. Specification, p. 11, lines 5-6. However, the layers in contact with the adhesive layer of Fig. 6 are either a rate controlling membrane **60E** ('129 patent, col. 13, line 15) that allows diffusion of an active solute (col. 1, line 50; col. 13, lines 13-17) or a release line **60C** (assuming "C" represents release liners in different views - see '129 patent, col. 12, lines 63-69; col. 13, lines 3-6). Therefore, Fig. 6 of the '129 patent does not truly teach a barrier layer attached to an active layer and an adhesion layer.

Moreover, none of the figures in the '129 patent discloses a fractional adhesion layer that covers less than the total side of the barrier layer. Because, as demonstrated above, the '129 patent does not disclose or suggest a fractional adhesion layer that covers less than the total area of a side of a barrier layer, independent claim 113 and claims 119 and 122, which depend from claim 113, are patentably distinguishable and allowable over the '129 patent.

Rejections Based on US 4,915,950

Claims 113 and 122 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. patent 4,915,950 ('950) to Miranda et al. However, the cited prior art does not meet all the limitations of the instant claims.

The Examiner asserts that Fig. 1 of the '950 patent meets all the limitations of claim 113. However, the Examiner's rejection does not discuss, and the '950 patent does not disclose, a fractional adhesion layer that covers less than the total area of a side of a barrier layer. To the contrary, Fig. 1 of the '950 patent clearly teaches an adhesive layer **12** that covers the entirety (extends to the limits of) a backing layer **11**. '950 patent, col. 4, lines 65-66. Therefore, the '950 patent does not teach every aspect of the instant claims, and correspondingly, claim 113 is patentably distinct over the '950 patent.

Moreover, the '950 patent does not teach a barrier layer with a first side attached to an active layer while the opposite side is attached to an adhesive layer. Assuming that the backing layer **11** of the '950 is equivalent to the barrier layer of the invention, the backing layer **11** is not in simultaneous contact with an active layer and an adhesive layer. Rather, the backing layer **11** is only in contact with the adhesive layer. For the

'950 patent to anticipate the instant claims, it must disclose the same elements in the same arrangement. It does not.

Claim 122 depends from claim 113 and, therefore, includes all the limitations of claim 113. Therefore, the fact that the '950 patent does not anticipate claim 113 allows for the patentability of dependent claim 122.

Because, as demonstrated above, the '950 patent does not disclose a fractional adhesion layer that covers less than the total area of a side of a barrier layer nor the same elements in the same arrangement, independent claim 113 and claim 122, which depends from claim 113, are patentably distinguishable and allowable over the '950 patent.

Rejections Based on US 5,352,456

Claims 113, 119 and 122 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. patent 5,352,456 ('456) to Fallon et al. However, the cited prior art does not meet all the limitations of the instant claims.

First, the '456 patent does not disclose the same elements in the same arrangement, as required by the instant claims. The '456 patent discloses a top impermeable backing layer **11**, a permeable backing layer **12**, an active layer (formed by the combination of a confined drug reservoir **13** and a permeable substrate layer **14**), an adhesive layer **15** and a release liner **16**. See '456 patent, col. 3, lines 14-28; '456 patent, Fig. 1. It does not disclose an impermeable barrier layer that is attached to both an active layer and an adhesive layer.

Second, the '456 patent does not disclose a fractional adhesion layer that covers less than the total area of a side of a barrier layer.

Because the '456 patent does not disclose an impermeable barrier layer that is attached to both an active layer and an adhesive layer or a fractional adhesion layer that covers less than the total area of a side of a barrier layer, independent claim 113, and claims 119 and 122 which depend from claim 113, are patentably distinguishable and allowable over the '456 patent.

Rejections Based on US 5,071,704

Claims 113, 119-120, 122 and 124-125 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. patent 5,071,704 ('704) to Fischel-Ghodsian. However, the cited prior art does not meet all the limitations of the instant claims.

The Examiner's rejection does not discuss, and the '704 patent does not disclose, a fractional adhesion layer that covers less than the total area of a side of a barrier layer. To the contrary, the '704 patent clearly teaches adhesive layers **38** and **48** that cover the entirety (extends to the limits of) a backing layer. '704 patent, Figs. 3-4; col. 7, line 61; col. 8, lines 48-49. In addition, the '704 patent does not disclose a release liner, as required by claim 113. Therefore, the '704 patent does not teach every aspect of the instant claims, and correspondingly, claim 113 is patentably distinct over the '704 patent.

Because, as demonstrated above, the '704 patent does not disclose or suggest a fractional adhesion layer that covers less than the total area of a side of a barrier layer or a release liner, independent claim 113, and claims 119-120, 122 and 124-125 which depend from claim 113, are patentably distinguishable and allowable over the '704 patent.

Summary

Applicants respectfully submit that claims 113, 119-125 and new claim 147 meet the novelty requirements under 35 U.S.C. § 102 and, therefore, request withdrawal of the rejections of these claims on the grounds of anticipation.

Rejections Under 35 U.S.C. § 103 – Obviousness

In order to produce a prima facie case of obviousness under 35 U.S.C. §103, an examiner must support his or her rejection with a clear articulation of the reasons why the claimed invention would have been obvious. MPEP § 2142. Ascertaining the differences between the prior art and the claims at issue requires that the claimed invention be considered as a whole. MPEP § 2141.02. Every limitation of a claim must be addressed. *See* MPEP § 2116.01.

In the present application, the Examiner fails to support a prima facie case of obviousness because the references and remarks accompanying the § 103 rejections address neither all the limitations of the claims nor how the differences between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.

US 5,071,704 in View of US 2003/0007944 or US 2003/0118533

The Examiner has rejected claims 113, 119-122 and 124-125 under 35 U.S.C. § 103(a) as being unpatentable over US 5,071,704 ('704) to Fischel-Ghodsian in view of US 2003/0007944 ('944; now U.S. patent no. 6,797,262) to O'Halloran et al. or US 2003/0118533 ('533; now U.S. patent no. 6,887,859) to Clapp et al. The Applicants note, however, that the rejection seems directed only to claim 121, which claims the use of polyurethane-1 in the patch of the invention.

The Examiner states that the '704 patent meets all the limitations of claims 113, 119-120, 122 and 124-125 except that it does not teach polyurethane. The Examiner states that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the specific polyurethane-1 of '944 or '533 into the composition of '704" to arrive at the instant claims. Office Action, p. 9. However, even assuming such a substitution would have been obvious, it still would not result in the invention of claim 121, which depends from claim 113 and includes a fractional adhesion layer.

As discussed above, the '704 patent does not teach a fractional adhesion layer that covers less than the total area of a side of a barrier layer, which is a necessary limitation of claim 113. It also does not disclose a release liner. The '944 and '533 publications further cited by the Examiner cannot cure these deficiencies because they also do not teach adhesive layers or release liners. Furthermore, the rejection does not discuss how such a fractional adhesion layer, release liner and the particular arrangement of components of the instant claims would have been obvious to one skilled in the art. Therefore, the rejection fails to address all the limitations of the instant claims and fails to disclose how the differences between them and the combined teachings of the prior art would have been obvious to one of ordinary skill in the art.

Given that the combination of the '944 and '533 publications with the '704 patent fails to result in the invention of the instant claims, the Examiner has failed to establish a *prima facie* case of obviousness.

**U.S. 5,352,456, U.S. 4,874,129 or U.S. 2002/0160035 in view of U.S.
2003/0007944 or US 2003/0118533**

The Examiner has rejected claims 113 and 119-122 under 35 U.S.C. § 103(a) as being unpatentable over U.S. 5,352,456 ('456), U.S. 4,874,129 ('129) or U.S. 2002/0160035 ('035) in view of U.S. 2003/0007944 ('944) or US 2003/0118533 ('533). The '944 and '533 publications are once again cited only to meet the limitations of claim 121.

All the references, and their inapplicability to, in combination, achieve the invention as now claimed, are discussed above and incorporated by reference to the rejection of claims 113 and 119-122. None of them, either alone or in combination, teach a fractional adhesion layer that covers a fraction of a total area of a side of a barrier layer, wherein the fraction is less than 1. Furthermore, the Examiner's discussion of the combination of these publications fails to even address this limitation.

Because the combination of cited references fails to result in the inventions of the instant claims, a *prima facie* case of obviousness has not been established.

**U.S. 5,071,704, U.S. 4,915,950, U.S. 5,352,456, U.S. 4,874,129 or U.S.
2002/0160035 in view of U.S. 5,589,122 or U.S. 6,129,983**

The Examiner has rejected claims 113, 119-120 and 122-125 under 35 U.S.C. § 103(a) as being unpatentable over U.S. 5,071,704 ('704), U.S. 4,915,950 ('950), U.S. 5,352,456 ('456), U.S. 4,874,129 ('129) or U.S. 2002/0160035 ('035) in view of U.S. 5,589,122 ('122) or U.S. 6,129,983 ('983). The Applicants note, however, that the rejection seems directed only to claim 123, which includes a limitation that the barrier layer is a double coated tape.

The Examiner's rejection does not address all of the limitations of claims 113, 119-120 and 122-125. It states only that it would have been obvious to one of ordinary skill in the art to combine the known method of making a double-sided adhesive tape as arguably disclosed in the '122 or '983 patents with the patch compositions of the other publications/patents. However, the rejection fails to address how the combination results in the instant claims. The deficiencies of the '704, '950, '456, '129 and '035 publications

are discussed above and incorporated herein by reference. The Examiner has not addressed how the '122 or '983 patents cure these deficiencies.

Moreover, to the extent that either the '122 or '983 patents disclose teachings that may be useful to arriving at the instant claims, those teachings are directed towards different ends than those of the instant claims, and a person of ordinary skill would not have thought to combine the '122 or '983 patents with the previously discussed prior art. For example, the '122 patent teaches a double-sided tape with an adhesive layer that has longitudinal channels that can function as finger tabs. '122 patent, col. 4, lines 35-47. The teachings of the '983 patent are directed to the composition and properties of the backing layer, principally its sealing properties. *See* '983 patent, abstract; col. 1., lines 3-8; col. 2., lines 6-14. Accordingly, the '983 patent teaches the desirability of increasing the adhesiveness of the tape. '983 patent, col. 3. lines 52-53. The inventions of the instant claims, on the other hand, utilize a fractional adhesion layer to assure the desired amount of adhesion between a patch and an external surface, while minimizing the amount of adhesive used. Specification, p. 12, lines 8-10. Furthermore, neither the '122 patent nor the '983 patent discloses the use of adhesion layers for use in a patch comprising an active layer. Therefore, one skilled in the art would not be inclined to combine '122 and '983 patents with the previously discussed prior art because the teachings of those patents are not directed towards minimizing the amount of adhesive used or assuring a desired amount of adhesion between a patch with an active layer and an external surface.

Given that the rejection neither addresses all of the limitations of the claims nor discusses how the differences between the instant claims and the prior art would have been obvious to one of skill in the art, a *prima facie* case of obviousness has not been established.

Summary

Applicants respectfully submit that claims 113, 119-125 and new claim 147 meet the nonobviousness requirements under 35 U.S.C. § 103 and, therefore, request withdrawal of the rejection of these claims on the grounds of obviousness.

Conclusion

For at least the reasons set forth above, Applicants respectfully submit that all claims presently in the application are believed to be allowable over the art of record and early notice to that effect is respectfully solicited. The Examiner is requested to telephone the undersigned at (617) 443-9292 if any matters remain outstanding so that they may be resolved expeditiously

Applicants do not believe any extension of time is required for timely consideration of this response. In the event that an extension has been overlooked, this conditional petition of extension is hereby submitted. Applicants request that deposit account number 19-4972 be charged for any fees that may be required for the timely consideration of this application.

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Respectfully submitted,

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